

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

o.k. to enter
1. (Currently Amended) A data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, ~~facility monitoring system~~, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

2. (Cancelled) The data management system of claim 1, wherein the facility monitoring system is from the group consisting of a HVAC monitoring system, air flow detector, humidity detector, pressure monitor, and thermometer.

3. (Original) The data management system of claim 1, wherein the water quality detector is selected from the group consisting of pH detector, conductivity detector, total organic content detector, endotoxin detector, coliform detector, metal detector, and thermometer.

4. (Original) The data management system of claim 1 wherein the U.S. Food and Drug Administration requirements are electronic records and electronic signature requirements.

5. (Original) The data management system of claim 1 wherein the U.S. Food and Drug Administration requirements are set forth in United States 21 CFR Part 11.

6. (Original) The data management system of claim 1 wherein the report is a configurable report having configurable records selected from the group consisting of data records to include, displayed fields, sort and grouping of data records, and formatting of data via a table, bar chart, pie chart, or other visual display.

7. (Original) The data management system of claim 1 further configured to allow a user to configure access of a specific individual with access to a predetermined specific system function.

8. (Original) The data management system of claim 1 wherein the electronic communication between the hub and the equipment is accomplished by a link device that interfaces with the equipment used to measure the environmental data.

9. (Original) A data management system having a universal hub, the universal hub interfacing with at least one add-on software module for specialized tracking of data unique for a particular manufacturing facility, the data selected from the group consisting of media growth promotion, sterility testing, media fills, bioburden, equipment maintenance and calibration, annual report, antibiotic assay, biological indicator, corrective and preventative action, cleaning and disinfection validation and tracking, container closure integrity, endotoxin testing, filter integrity, package integrity, preservative effectiveness testing, and smoke studies, the system configured to collect and store the data, and generate a user report of the data, the user report providing document compliance with U.S. Food and Drug Administration requirements.

10. (Original) The data management system of claim 9 wherein the U.S. Food and Drug Administration requirements are electronic records and electronic signature requirements.

11. (Original) The data management system of claim 9 wherein the U.S. Food and Drug Administration requirements are set forth in United States 21 CFR Part 11.

12. (Original) The data management system of claim 9 wherein the report is a configurable report having configurable records selected from the group consisting of data records to include, displayed fields, sort and grouping of data records, and formatting of data via a table, bar chart, pie chart, or other visual display.

13. (Original) The data management system of claim 9 further configured to allow a user to configure access of a specific individual with access to a predetermined specific system function.

14. (Currently Amended) A data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure a first set of data, the system configured to collect and store the first set of data, and generate a first user report of the first set of data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, ~~facility monitoring system~~, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the universal hub interfacing with at least one add-on software module for specialized tracking of a second set of data, the second set of data unique for a particular manufacturing facility, the second set of data selected from the group consisting of media growth promotion, sterility testing, media fills, bioburden, equipment maintenance and calibration, annual report, antibiotic assay, biological indicator, corrective and preventative action, cleaning and disinfection validation and tracking, container closure integrity, endotoxin testing, filter integrity, package integrity, preservative effectiveness testing, and smoke studies, the system configured to collect and store the second set of data, and generate a second user report of the second set of data, the first and second user reports providing document compliance with U.S. Food and Drug Administration requirements.

15. (Cancelled) The data management system of claim 14, wherein the facility monitoring system is from the group consisting of a HVAC monitoring system, air flow detector, humidity detector, pressure monitor, and thermometer.

16. (Original) The data management system of claim 14 wherein the water quality detector is selected from the group consisting of pH detector, conductivity detector, total organic content detector, endotoxin detector, coliform detector, metal detector, and thermometer.

17. (Original) The data management system of claim 14 wherein the U.S. Food and Drug Administration requirements are electronic records and electronic signature requirements.

18. (Original) The data management system of claim 14 wherein the U.S. Food and Drug Administration requirements are set forth in United States 21 CFR Part 11.

19. (Original) The data management system of claim 14 wherein the first and second user reports are configurable reports having configurable records selected from the group consisting of data records to include, displayed fields, sort and grouping of data records, and formatting of data via a table, bar chart, pie chart, or other visual display.

20. (Original) The data management system of claim 14 further configured to allow a user to configure access of a specific individual with access to a predetermined specific system function.

21. (Original) The data management system of claim 14 wherein the electronic communication between the hub and the equipment is accomplished by a link device that interfaces with the equipment used to measure the first set of data.

22. (Currently Amended) A computer-readable medium having computer-executable instructions for performing the steps of:

- a) collecting environmental data from a piece of equipment used to automatically measure environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, ~~facility monitoring system~~, rapid organism enumeration technology device, bioluminescence device, and water quality detector;
- b) storing the collected environmental data; and
- c) generating a user report of the environmental data, the user report providing document compliance with U.S. Food and Drug Administration requirements.

23. (Original) The computer-readable medium of claim 22 wherein the U.S. Food and Drug Administration requirements are electronic records and electronic signature requirements.

24. (Original) The computer-readable medium of claim 22 wherein the U.S. Food and Drug Administration requirements are set forth in United States 21 CFR Part 11.

25. (Original) The computer-readable medium of claim 22 having further computer-executable instructions for performing the step of configuring the report for certain items, the certain items selected from the group consisting of data records to include, displayed fields, sort and grouping of data records, and formatting of data via a table, bar chart, pie chart, or other visual display.

26. (Original) The computer-readable medium of claim 22 having further computer-executable instructions for performing the step of configuring access of a specific individual with access to a predetermined specific system function.

27. (Original) A computer-readable medium having at least one computer-executable module for specialized tracking of data unique for a particular manufacturing facility, the data selected from the group consisting of media growth promotion, sterility testing, media fills, bioburden, equipment maintenance and calibration, annual report, antibiotic assay, biological indicator, corrective and preventative action, cleaning and disinfection validation and tracking, container closure integrity, endotoxin testing, filter integrity, package integrity, preservative effectiveness testing, and smoke studies, the module having computer-executable instructions for performing the steps of

- a) collecting the data;
- b) storing the collected data; and

c) generating a user report of the environmental data, the user report providing document compliance with U.S. Food and Drug Administration requirements.

28. (Original) The computer-readable medium of claim 27 wherein the U.S. Food and Drug Administration requirements are electronic records and electronic signature requirements.

29. (Original) The computer-readable medium of claim 27 wherein the U.S. Food and Drug Administration requirements are set forth in United States 21 CFR Part 11.

30. (Original) The computer-readable medium of claim 27 having further computer-executable instructions for performing the step of configuring the report for certain items, the certain items selected from the group consisting of data records to include, displayed fields, sort and grouping of data records, and formatting of data via a table, bar chart, pie chart, or other visual display.

31. (Original) The computer-readable medium of claim 27 having further computer-executable instructions for performing the step of configuring access of a specific individual with access to a predetermined specific system function.